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EXAMINER

WIEST, PHILIP R

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/509,673  
Filing Date: October 08, 2004  
Appellant(s): NAGAO ET AL.

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Daniel A. Geselowitz  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/1/10 appealing from the Office  
action mailed 10/1/09.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, and 5-25 are pending, rejected, and under appeal. Claims 2 and 4 have been cancelled.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

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subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

4,602,910	Larkin	7-1986
5,423,421	Inoue	6-1995
6,319,243	Becker	11-2001

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 5, 6, 9-12, 14-16, 17-20, and 22-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Larkin (US 4,602,910).

With respect to Claims 1, 3, 5, 6, 9-12, 15, 17-20, 23, and 25 Larkin teaches a multiple-chamber medical container comprising a container body having multiple chambers (between sheets 15 and 18 and between sheets 37 and 18, see Figure 3) that are capable of containing medicaments therein, and a partitioning seal 43 that separates the first and second chambers from each other. The system further comprises a medicinal outlet portion attached to the container body for discharging the medicaments from the chamber therethrough, and an openable small container 36

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having a medicament 50 (such as an antibiotic) therein positioned within the first chamber 18 (see Figure 5). The partitioning seal portion 43 is formed by separably bonding opposing inner wall surfaces of the container body, as shown in Figures 4 and 5. The small chamber comprises a multi-layer film (Fig. 6) that is heat sealed and is structured to open in response to external force, and has a bonded portion 44 adjacent the partitioning seal 43 and bonded to the container body, wherein the bonded portion comprises opposing outer surfaces of sheet material, wherein the opposing outer surfaces are each bonded to the opposing inner wall surfaces of the container body in the vicinity of the partitioning seal portion. The small container is positioned partly inserted into the partitioning seal portion and is opened in accordance with the separation of the walls (15, 18) of the container body.

With specific regard to the recitation that the partitioning seal is formed by separably bonding opposing inner wall surfaces of the container body, the claimed phrase is being treated as a product by process limitation; that is, that the partitioning seal is formed by separably bonding opposing inner wall surfaces of the container body. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Larkin is silent as to the process used to create the partition seal, it appears that the product in Larkin would be the same or similar as that claimed; especially since both applicant's product and the prior art

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product is made of a flexible plastic material that is bonded together at certain points to create a plurality of chambers.

With respect to Claims 14 and 22, Larkin teaches a mandrel-type seal 32 to prevent discharge of fluid until the seal is broken.

With respect to Claims 16 and 24, the bag of Larkin is fully capable of being placed inside a bag and arranged in any position. If applicant amends the claims to add structure to the bag, the examiner reserves the right to impose a restriction requirement between the bag and the container.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin in view of Inoue (US 5,423,421). Larkin teaches the device substantially as claimed, but does not specifically disclose that the seal comprises a plurality of bonded parts arranged with at least one non-bonded part therebetween. Inoue discloses a multichamber container for mixing medical fluids, wherein a small container is fluidly connected to a large container by a separable bonded section. The bonded section is configured such that it becomes delaminated when sufficient pressure is applied (see figure 4). Furthermore, the bonded section comprises a non-bonded portion 9 in the center of the bonded portion. This configuration reduces the amount of sealing that is performed, thereby reducing the strength of the seal to make it easier to open, and eliminates the likelihood that the sealing operation will thermally degrade the medicinal preparations accommodated in the chambers (Column 4, Line 63 through Column 5, Line 37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medicament mixing device of Larkin with the unsealed

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portion of the bonded section of Inoue in order improve the breakability of the seal and prevent heat damage to the medicaments stored within the device.

Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin in view of Becker (US 6,319,243). Larkin teaches the device substantially as claimed, but does not specifically disclose that the small container is disposed in the same chamber as the outlet portion. Becker discloses a multichamber container for mixing medicaments, wherein a plurality of breakable seals (18, 20) are positioned between the chambers, therefore allowing selective mixing of the chambers (see Figures 1 and 2). Becker further discloses a plurality of outlets (31, 32, 34) (one in each chamber), such that fluid may be selectively drained from any of the chambers. This would allow, for example, fluids from two of the three chambers to be mixed together and drained, without mixing the fluid with the third chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medical fluid mixing device of Barney and Larkin with Becker's use of a plurality of fluid outlets (i.e. one in each chamber), such that fluids could be mixed and drained in a variety of ways. It may not always be desirable to mix all the medicaments together, and placing an outlet in the same chamber as the smaller chamber would allow those fluids to be selectively mixed.

#### **(10) Response to Argument**

Regarding the 102 rejection of claims 1 and 3, appellant presents the following arguments (see pages 14-22 of brief):

**First**, appellant argues that Larkin's device does not teach both a partitioning seal portion formed by separably bonding opposing inner wall surfaces of the container body and a bonded portion comprising opposing outer surfaces of the small container sheet material that are bonded to the opposing inner surfaces of the container body. This argument has not been found persuasive. As shown in Figure 4 below, Larkin teaches both of these structural elements as claimed.

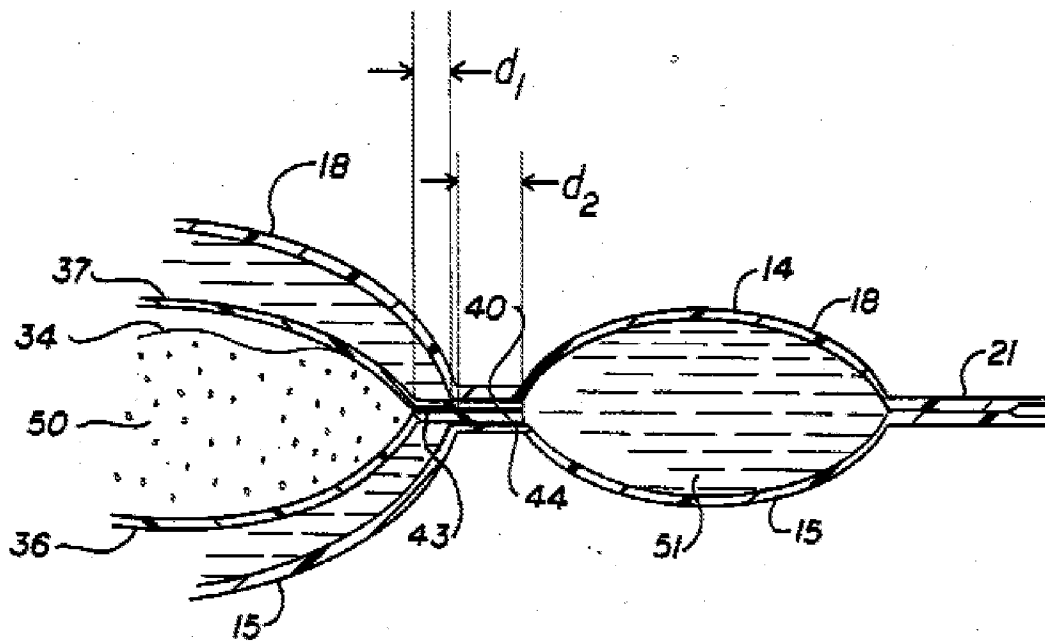


FIG. 4

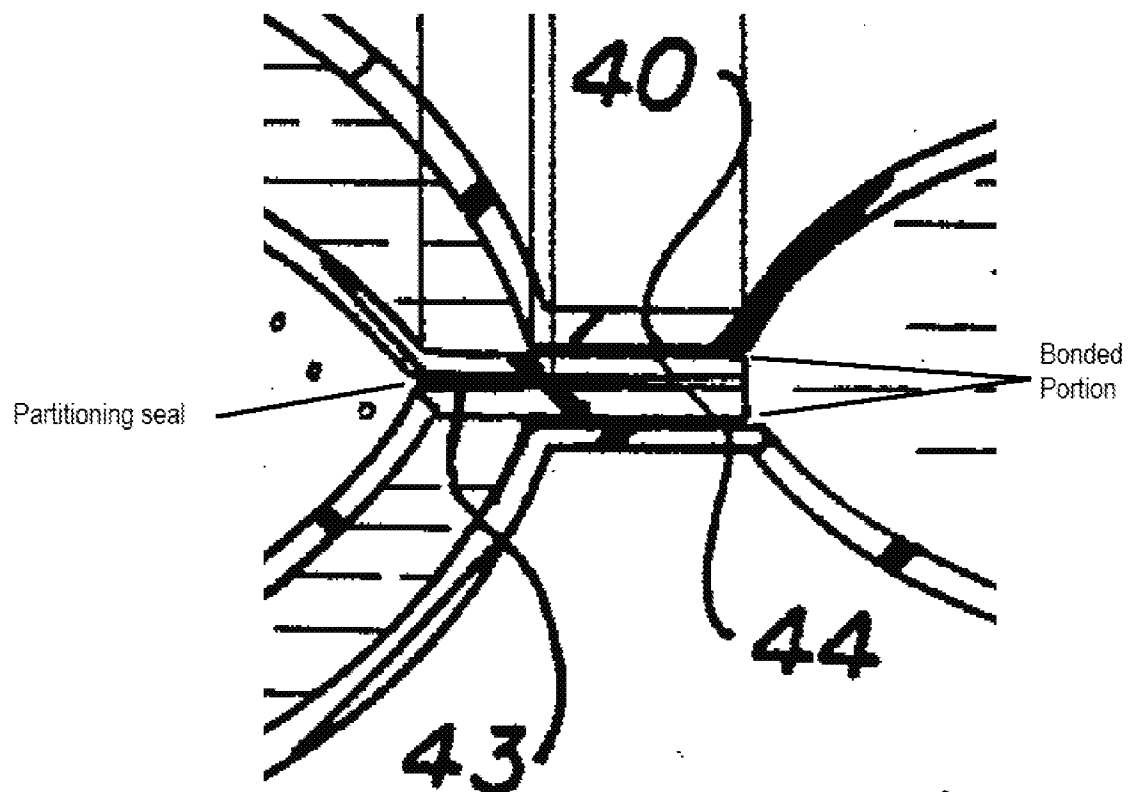
**Regarding the partitioning seal**, Larkin clearly teaches a small container that is separated from a larger container by means of a partitioning seal 43, said partitioning seal being formed by separably bonding opposing inner wall surfaces of sheets 36 and 37 of the container body. This structural arrangement meets the limitations of claims 1 and 3. Further, with specific regard to Claim 3, the partitioning seal is made of sheets



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that form the small container. Therefore, the small container is *at least partially* inserted into the region containing the partitioning seal.

**Regarding the bonded portion**, Larkin clearly teaches that the small container is bonded to the rest of the container body by means of a bonded portion (40, 44), said bonded portion comprising opposing outer surfaces of sheets 36 and 37 being bonded to the opposing inner wall surfaces of the chambers (i.e. the inner walls of sheets 15 and 18) in the vicinity of the partitioning seal 43. This structural arrangement meets the limitations of claims 1 and 3.



Therefore, Larkin teaches that the partitioning seal 43 and bonded portion (40, 44) are *two separate elements*. Further, Appellant specifically argues that there is no

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location where back wall 18 is bonded to the front wall. However, the claims do not state that walls 15 and 18 are **DIRECTLY** bonded to one another. Walls 15 and 18 are indirectly bonded together as part of the bonded portion and the partition seal.

**Second**, appellant argues that Larkin only teaches one chamber for containing medicaments, while the claims call for “multiple chambers for containing medicaments.” This argument has not been found persuasive. It is important to note that appellant *does not claim two chambers that are configured to contain medicaments and configured to mix with one another*. Appellant’s claim language of “multiple chambers for containing medicaments” means that Larkin must merely teach a plurality of chambers that are CAPABLE of containing medicaments. In this case, Larkin teaches a container system comprising a plurality of chambers (between sheets and between sheets 37 and 18) that contain or are fully capable of containing a liquid. These chambers are FULLY CAPABLE of holding any type of medicament.

Regarding the 103 rejection in view of Larkin, appellant argues that there is no motivation to modify Larkin to (1) have a further partitioning seal in the vicinity of and partially inserted within the small container, and (2) to fill both chambers with a medicament (see pages 23-27 of brief). However, as discussed above, Larkin ANTICIPATES both of these features.

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Regarding the 103 rejections of claims 7, 8, 13, and 21, appellant's arguments are based on the grounds that Larkin does not teach all structural elements of claims 1 and 3. However, as discussed above, Larkin teaches these elements.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Philip R Wiest/

Examiner, Art Unit 3761

Conferees:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

/Leslie R. Deak/

Primary Examiner, Art Unit 3761